

NOV 30 2004

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TO: Commissioner for Patents FROM: Mark DiPietro
Attn: Petitions Examiner Brian Hearn and Examiner A. Corbin
 P.O. Box 1450 TELEPHONE: 612.371.5375
 Alexandria, VA 22313-1450 Total pages, including cover letter: 17
1-703-272-6306
 PTO FAX NUMBER 1-571-273-1399 Our Docket No. 8436.18USRE

If you do NOT receive all of the pages, please telephone us at 612.332.5300, or fax us at 612.332.9081.

Documents Transmitted: COPIES OF PREVIOUSLY SUBMITTED DOCUMENTS:
New Alternative Requests and Response to Decision Denying Petition; Petition Under 37 C.F.R. 1.182 to Correct the Record in Error Regarding Term or to Amend the Terminal Disclaimer Filed in Error to a Joint Mistake by Applicants and the Patent Office Examiner; Terminal Disclaimer to Obviate a Double Patenting Rejection; and Certificate of Correction.

Applicant: LEE et al.
 Serial No.: 09/933,918
 Filed: 08/21/2001
 Group Art Unit: 1761
 Our Ref. No.: 8436.18USRE
 Confirmation No. 2055

FEES HAVE BEEN PREVIOUSLY PAID from Deposit Account No. 13-2725 in the amount of \$130.00 for Petition Fee (Fee Code 1460); \$110.00 for Terminal Disclaimer (Fee Code 1814/2814); and \$100.00 for Certificate of Correction (Fee Code 1811) for . Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate.

By: Mark DiPietro
 Name: Mark DiPietro
 Reg. No.: 28,707

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on the date shown below.

Darlene M. Stack

Darlene M. Stack
Signature

29 NOV '04
Date

NOV 30 2004

PATENT S/N 09/933,918

REISSUE PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-------------------|---|----------------------|------------------|
| Patent Applicant: | LEE ET AL. | Examiner: | ARTHUR L. CORBIN |
| Serial No.: | 09/933,918 | Group Art Unit: | 1761 |
| Filed | 08/21/2001 | Docket No.: | 8436.18USRE |
| Confirmation No.: | 2055 | Original Patent No.: | 5,637,345 |
| Title: | METHOD OF MANUFACTURING POWDERED DEER BLOOD | | |

NEW ALTERNATIVE REQUESTS AND RESPONSE TO DECISION DENYING PETITION

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Dear Sir:

This communication is in response to the Decision Denying Petition in Paper No. 8 mailed 28 June 2004.

Petitioners include a newly presented petition with alternative results for resolving this matter. Petitioners note the denial of the petition to withdraw the terminal disclaimer recorded against the patent and the finality of that position.

Summary of Position

1. The Office position appears to be that based on the case *Bayer AG v. Carlsbad Technology, Inc.* (a copy of the case is enclosed). The Office has apparently taken the position that it is not permitted to withdraw the terminal disclaimer under any circumstances. We believe the Office has read the *Bayer* case too broadly. The *Bayer* case holds that a patentee is not entitled to withdrawal of a terminal disclaimer that was correct as filed when the term of the underlying patent changes based on the Uruguay Rounds changes. In *Bayer*, the Office took the position that the term of the patent was changed by operation of law due to the Uruguay Rounds. The holding of the *Bayer* case, having a disclaimer correct on its face, is inappropriate with respect to the facts of the current case involving an error clear on its face in an erroneously filed terminal disclaimer. The Office is empowered to correct a clear error by statute.

2. The *Bayer* case establishes that the Office has the authority to either (1) recognize the correct term of the patent, or (2) correct an erroneously filed paper to accord the appropriate patent term. Neither of these steps is barred by the *Bayer* case.

3. Please find enclosed with this paper, a new petition to correct the record of the patent regarding disclaimer term or to amend an erroneous terminal disclaimer due to a joint error by Applicants and Patent Office.

Detailed Discussion

The facts in this case are simple and clear. In response to an Examiner's double patenting rejection, Applicants filed a disclaimer listing a clearly erroneous patent (U.S. Patent No. 5,460,677). The listed patent (U.S. Patent No. 5,460,677) was different than the one cited by the Examiner (U.S. Patent No. 5,505,980) in the referenced rejection. The Examiner reviewed the paper and did not recognize the error in the terminal disclaimer. Clearly, the error was made initially by the Applicants' attorney and compounded by the Examiner in subsequent proceedings. The error is plain on the face of the paper if reviewed by anyone knowledgeable about Double Patenting rejections and Terminal Disclaimer practice. The effect of the erroneous terminal disclaimer results in a substantial reduction of the term due assignee of the patent. The terminal disclaimer, clearly on its face, is not a general disclaimer of any term, aspect of the property right, but is intended to be a terminal disclaimer limiting the term of the issued patent to the term of a patent derived from a related application.

The facts of this case are clearly different than the facts in the *Bayer* case relied on by the Patent Office. In the *Bayer* case, Applicants filed a terminal disclaimer that was correct in all aspects when filed. The change circumstances involve the passage of the Uruguay Rounds statutes relating to the patent term. In the *Bayer* case, the Patent Office took the position that a correct terminal disclaimer could not be withdrawn. Because of the operation of law, the term of the patent was adjusted in light of the new law and the patent term changed by operation of law. The *Bayer* case states as follows:

Although finding that the URAA amendments created an ambiguity [**11] in Bayer's original terminal disclaimer, the PTO declined Bayer's request to withdraw the original disclaimer and substitute a new one. The PTO explained that the rules of practice did not provide for the

withdrawal of a terminal disclaimer. Decision, at 3, Section 253, which permits filing of a terminal disclaimer and "dedication to the public" of the terminal part of the term, does not include a mechanism for withdrawal or amendment of a terminal disclaimer. 35 U.S.C. § 253. Under 35 U.S.C. § 253, the PTO considers the terminal disclaimer part of the original patent. The PTO also noted that the clarification of the disclaimed date was not the correction of a clerical or typographical mistake under 35 U.S.C. § 255 and 37 C.F.R. § 1.323. Decision, at 2-3

Based on this portion of the case, the court clearly is indicating that, in the presence of a "clerical or typographical mistake", then the patent terms or the terminal disclaimer can be modified or corrected. The patent statute and Rules of Practice in 37 C.F.R. § 1.322 and § 1.323 clearly indicate that mistakes made by office or Applicant can be corrected in Reissue.

In the second full paragraph on page 5 of the Decision, the Petitions Examiner appears to suggest that no mistake has been made in this case. Applicants assert that this is clearly not so. The incorrect citation of a patent totally unrelated to the double patenting rejection and totally unrelated to terminal disclaimer practice is clear error on its face. The Patent Office cannot take the position that the terminal disclaimer in this case is a general disclaimer of patent term unrelated to the Double Patenting rejection.

In the third full paragraph of the Decision, the Examiner discusses the effect of any correction on the public. Applicants assert that the error was plain on the face of the file history of the patent and plain on the face of the patent. Any reader of the file history will note the filing of the original request to correct the record with a Certificate of Correction. The original attempt to correct combined with an inappropriate patent number would immediately alert members of the public, reading the patent or its file history, to the error. In fact, most practitioners seeing the disclaimer on the face of the patent would immediately assume that the term was limited to the term of the patent arising from the related filings. The public is not harmed by this change since, on the whole, a review of the file history would leave the typical practitioner to understand that the terminal disclaimer operated to limit the term to the related patent and not the erroneously listed patent.

By operation of law, the correct application of the terminal disclaimer in a double patenting rejection would result in a term limited to the related patent, not an unrelated patent.

Accordingly, the correction of the terminal disclaimer would not change the scope of the claims that is governed by operation of the law of double patenting and terminal disclaimers. No manifest unfairness relates to the public, since the public would recognize on the face of the Patent and the file history that the listed patent number was incorrect and would immediately recognize the appropriate term for the patent.

Respectfully submitted,

21 Nov'04

Date

Mark DiPietro

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PATENT TRADEMARK OFFICE

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1 of 1 DOCUMENT

BAYER AG and BAYER CORPORATION, Plaintiffs-Appellees, v. CARLSBAD TECHNOLOGY, INC., Defendant-Appellant.

02-1077

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

298 F.3d 1377; 2002 U.S. App. LEXIS 16710; 64 U.S.P.Q.2D (BNA) 1045

August 14, 2002, Decided

SUBSEQUENT HISTORY: [**1] Rehearing and Rehearing En Banc Denied September 23, 2002, Reported at: 2002 U.S. App. LEXIS 21335.

PRIOR HISTORY:Appealed from: United States District Court for the Southern District of California Senior Judge Rudi M. Brewster.

DISPOSITION: AFFIRMED.

LexisNexis(R) Headnotes

COUNSEL: Fred H. Bartlit, Jr., Bartlit Beck Herman Palenchar & Scott, of Chicago, Illinois, argued for plaintiffs-appellees. With him on the brief were Mark L. Levine and Sean W. Gallagher. Of counsel on the brief were Charles W. Bradley and Stanley L. Amberg, Orrick, Herrington & Sutcliffe LLP, of New York, New York. Also of counsel on the brief were Bruce R. Genderson, Margaret A. Keeley, and Aaron P. Maurer, Williams & Connolly LLP, of Washington, DC.

Gary M. Hnath, Venable, Baetjer, Howard & Civiletti, LLP, of Washington, DC, argued for defendant-appellant. With him on the brief was Fei-Fei Chao.

JUDGES: Before RADER, GAJARSA, and PROST, Circuit Judges.

OPINION BY: RADER

OPINION: [*1378] RADER, Circuit Judge.

On summary judgment, the United States District Court for the Southern District of California held that the expiration date of U.S. Patent No. 4,670,444 (the '444

patent) is December 9, 2003. Because the district court correctly concluded as a matter of law that the disclaimed term of the '444 patent was "due to" U.S. Patent No. 4,544,658, whose expiration date [**2] the Uruguay Round Agreements Act (URAA) amendments automatically changed from October 1, 2002 to December 9, 2003, this court affirms.

I.

Bayer AG and Bayer Corporation (collectively Bayer) filed a patent application on May 29, 1984 that ultimately issued as the '444 patent on June 2, 1987. The subject matter of the '444 patent includes the antibiotic ciprofloxacin sold by Bayer under the brand name CIPRO (R). Bayer also obtained two related patents covering ciprofloxacin: U.S. Patent No. 4,544,658 issued on October 1, 1985 (the Peterson '658 patent) and U.S. Patent No. 4,556,658 issued on December 3, 1985 (the Grohe '658 patent).

In December 1991, Barr Laboratories, Inc. (Barr) notified Bayer of Barr's Abbreviated New Drug Application (ANDA) submission to the Food and Drug Administration (FDA). Barr alleged that the '444 patent was invalid and unenforceable due to obviousness, obviousness-type double patenting, and inequitable conduct. In response, Bayer filed an infringement suit against Barr in the United States District Court for the Southern District of New York. To counter Barr's allegation of double patenting of the '444 patent over the two '658 patents, Bayer filed a terminal [**3] disclaimer with the United States Patent and Trademark Office (PTO). Bayer AG v. Barr Lab., Inc., 798 F. Supp. 196, 24 U.S.P.Q.2D (BNA) 1864 (S.D.N.Y. 1992).

On February 21, 1992, Bayer disclaimed "the terminal part of U.S. Patent No. 4,670,444 which

Page 2

298 F.3d 1377, *; 2002 U.S. App. LEXIS 16710, **;
64 U.S.P.Q.2D (BNA) 1045

extends beyond October 01, 2002, the earlier of the expiration dates of U.S. Patent Nos. 4,544,658 (issued October 01, 1985) and 4,556,658 (issued December 03, 1985)." Terminal Disclaimer filed February 21, 1992 (Terminal Disclaimer). This disclaimer language is the source of the present dispute. The April 21, 1992, issue of the PTO's Official Gazette carried a notice of the disclaimer stating: "The term of this patent subsequent to October 1, 2002, has been disclaimed."

In 1994, the URAA "harmonized the term provision of United States patent law with that of our leading trading partners which grant a patent term of 20 years from the date of filing of the patent application." Merck & Co. v. Kessler, 80 F.3d 1543, 1547, 38 U.S.P.Q.2D (BNA) 1347, 1349 (Fed. Cir. 1996). The URAA took effect on June 8, 1995, changing the patent term from seventeen years from the date of issuance to twenty years from the date of filing [**4] of the patent application. 35 U.S.C. § 154(a)(2) (2000). In addition, § 154(c)(1) allows "the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers." Id. § 154(c)(1). Consequently, the expiration date of the Peterson '658 patent changed from October 1, 2002 (seventeen years from grant) to December 9, 2003 (twenty years from filing of application) by operation of law.

[*1379] On July 10, 1995, Bayer sought to reflect the change that the URAA made on the term of the '444 patent by submitting an "amended terminal disclaimer" and a "communication submitting amended terminal disclaimer." Bayer requested the PTO amend the terminal disclaimer filed February 21, 1992 with new wording that "disclaims the terminal part . . . which would extend beyond the earlier of the expiration dates of the full statutory term . . . of U.S. Patent Nos. 4,544,658 . . . and 4,556,658" or, alternatively, to consider the communication a petition. The amended terminal disclaimer did not recite a specific date, but only referred to the expiration dates of the two '658 patents.

In view of the URAA, the PTO found Bayer's original [**5] disclaimer ambiguous in that "it sets forth two (2) dates beyond which the terminal part of the '444 patent is disclaimed: October 1, 2002, and December 9, 2003." Decision on petition, Application No. 06/614,923, at 5 (Jan. 31, 1996) (Decision). The PTO responded that its rules of practice did not permit withdrawal of a terminal disclaimer in favor of an amended terminal disclaimer. Nonetheless, in considering Bayer's request as a petition under its discretionary authority, * the PTO stated:

In view of the ambiguity in the terminal disclaimer filed February 21,

1992 created by the changes to 35 U.S.C. § 154(c)(1) contained in Public Law 103-465, Office records will be changed to indicate that the term of the above-identified patent subsequent to December 9, 2003, the later of the two (2) dates set forth in the terminal disclaimer filed on February 21, 1992, has been disclaimed.

Id.

* The Patent and Trademark Office (PTO) treated Bayer's communication as a petition under 37 C.F.R. § 1.182. Decision, at 1. 37 C.F.R. § 1.182 (2002) states: "All situations not specifically provided for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Commissioner, subject to such other requirements as may be imposed, and such decision will be communicated to the interested parties in writing. Any petition seeking a decision under this section must be accompanied by the petition fee set forth in § 1.17(h)."

[**6]

In April 2001, Carlsbad Technology, Inc. (CTI) notified Bayer of its ANDA on ciprofloxacin. Bayer filed suit in the district court in May 2001, asserting that the '114 patent on ciprofloxacin was valid until December 9, 2003. CTI counterclaimed that the ciprofloxacin claims in the '444 patent expire on October 1, 2002. The parties dispute whether the inclusion of the "October 01, 2002" date in the February 21, 1992 terminal disclaimer created an ambiguity as to the relationship between the '444 patent and the two '658 patents. Bayer and CTI cross-moved for summary judgment. The district court denied CTI's motion and granted summary judgment in favor of Bayer. Bayer AG v. Carlsbad Tech., Inc., 2001 U.S. Dist. LEXIS 24487, Civ. No. 01-867-B (LSP), slip op. at 11 (S.D. Cal. Nov. 1, 2001) (Summary Judgment). CTI timely appealed to this court, which has jurisdiction under 28 U.S.C. § 1295(a)(1).

II.

This court reviews a district court's grant of summary judgment without deference. Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1353, 47 U.S.P.Q.2D (BNA) 1705, 1713 (Fed. Cir. 1998). This court must decide "if the pleadings, depositions, answers to interrogatories, and admissions [*67] on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P.

Page 3

298 F.3d 1377, *; 2002 U.S. App. LEXIS 16710, **;
64 U.S.P.Q.2D (BNA) 1045

56(c); Celotex Corp. v. [**1380] Caietti, 477 U.S. 317, 322, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986). In making this determination, this court views the record in a light most favorable to the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986); C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc., 911 F.2d 670, 672-73, 15 U.S.P.Q.2D (BNA) 1540, 1542-43 (Fed. Cir. 1990).

CTI does not dispute the facts of this case. Rather, it challenges the district court's application of the URAA to Bayer's original terminal disclaimer which upheld the PTO's determination that the '444 patent expires on December 9, 2003. CTI asserts that the 1992 disclaimer clearly and unambiguously fixed the '444 patent's expiration date to October 1, 2002. CTI notes that the PTO published the October 2002 date in the Gazette, indicating that the disclaimer set the expiration date for October 1, 2002.

Title 35 of the United States [**8] Code as amended in light of the URAA, states:

(a)(2) Term. Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

(c)(1) Determination. The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

35 U.S.C. § 154 (a)(2) and (c)(1). In response to public comments on its rules to implement the new twenty-year term, the PTO stated:

A patent that is in force on June 8, 1995, or a patent that issues after June 8, 1995, on an application filed before June 8, 1995, is automatically entitled to the [**9] longer of the 20-year patent term measured from the earliest U.S. effective

filing date or 17 years from grant. This is automatic by operation of law. Patentees need not make any election to be entitled to the longer term.

Changes to Implement 20-Year Patent Term and Provisional Applications, 60 Fed. Reg. 20,195, 20,207 (April 25, 1995) (emphasis added).

In the present case, Bayer's February 21, 1992 terminal disclaimer recites in pertinent part:

Bayer . . . disclaims the terminal part of U.S. Patent No. 4,670,444 which extends beyond October 01, 2002, the earlier of the expiration dates of U.S. Patent Nos. 4,544,658 (issued October 01, 1985) and 4,556,658 (issued December 03, 1985), and hereby agrees that U.S. Patent No. 4,670,444 shall be enforceable only for and during such period that legal title to U.S. Patent No. 4,670,444 shall be the same as legal title to U.S. Patent Nos. 4,544,658 and 4,556,658.

(Emphases added.) This disclaimer expressly sets the expiration date of the '444 patent at the "earlier of the expiration dates" of the two '658 patents. Before the URAA amendments took effect on June 8, 1995, the earlier of the [**10] expiration dates of the two '658 patents was October 1, 2002, i.e., seventeen years from date of issuance of the Peterson '658 patent. Hence, when filed in 1992, the language of the terminal disclaimer set the expiration date for the '444 patent for October 2002.

[**1381] When the URAA amendments took effect on June 8, 1995, however, the earlier of the two expiration dates became December 9, 2003, i.e., twenty years from the date of filing of the Peterson '658 patent. 35 U.S.C. § 154(a)(2). This extension of patent term on the Peterson '658 patent was "automatic by operation of law." 60 Fed. Reg. at 20,207. Consequently, the terminal disclaimer of the '444 patent, as tied to the Peterson '658 patent, moved the expiration date of the '444 patent automatically to December 9, 2003. The disclaimer also mentioned the October 2002 date. In that situation, the PTO detected an ambiguity because the disclaimer now contained two dates: October 1, 2002 and December 9, 2003. The district court correctly relied on the PTO's analysis of the law and of the language of the original terminal disclaimer.

Although finding that the URAA amendments created an ambiguity [**11] in Bayer's original terminal disclaimer, the PTO declined Bayer's request to withdraw the original disclaimer and substitute a new one. The PTO explained that the rules of practice did not

298 F.3d 1377, *; 2002 U.S. App. LEXIS 16710, **;
64 U.S.P.Q.2D (BNA) 1045

provide for the withdrawal of a terminal disclaimer. Decision, at 3. Section 253, which permits filing of a terminal disclaimer and "dedication to the public" of the terminal part of the term, does not include a mechanism for withdrawal or amendment of a terminal disclaimer. 35 U.S.C. § 253. Under 35 U.S.C. § 253, the PTO considers the terminal disclaimer part of the original patent. The PTO also noted that the clarification of the disclaimed date was not the correction of a clerical or typographical mistake under 35 U.S.C. § 255 and 37 C.F.R. § 1.323. Decision, at 2-3.

Nonetheless, because 35 U.S.C. § 154(a)(2) automatically extended the term of the Peterson '658 patent by operation of law, 60 Fed. Reg. at 20,207, the PTO corrected its records to indicate that Bayer had disclaimed the term of the '444 patent beyond December 9, 2003 in accordance with. [**12] 35 U.S.C. § 154(c)(1). Decision, at 6. The district court correctly sustained the PTO's actions as a proper exercise of its authority under 37 C.F.R. § 1.182.

The district court properly accorded deference to the PTO's implementing regulations and to the PTO's interpretive "Decision", which it found complied with 35 U.S.C. §§ 154 (a)(2) and (c)(1), in accordance with Skidmore v. Swift & Co., 323 U.S. 134, 140, 89 L. Ed. 124, 65 S. Ct. 161 (1944). See also Merck, 80 F.3d at 1550; United States v. Cleveland Indians Baseball Co., 532 U.S. 200, 220, 149 L. Ed. 2d 401, 121 S. Ct. 1433 (2001) ("Because [the agency's] interpretation [of its own regulation] is reasonable, it attracts substantial judicial deference."); Dethmers Mfg. v. Automatic Equip. Mfg., 272 F.3d 1365, 1379, 60 U.S.P.Q.2D (BNA) 1929, 1939 (Fed. Cir. 2001) (Dyk, J., concurring-in-part and dissenting-in-part) ("We are obligated by clear Supreme Court precedent to give deference to the PTO's own interpretation of its regulations."). The PTO thoroughly considered the effect of the URAA on this terminal disclaimer and gave persuasive reasons for correcting [**13] its records to reflect the December 2003 expiration date for the '444 patent.

Beyond deference to the PTO analysis, the district court also examined the meaning and effect of the URAA. As noted, the URAA states that the "term of a patent . . . shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant." 35 U.S.C. § 154(c)(1) (2000). This language mandates the automatic substitution of a later expiration date for the prior expiration date of the Peterson '658 patent. Because Bayer linked its terminal disclaimer to the expiration date of the Peterson '658 patent, the terminal disclaimer date also automatically shifted to December 2003.

[**1382] As the district court noted, the Senate Report on the URAA confirms this meaning of the statutory language as applied to terminal disclaimers:

A patent whose term has been under section 235 of Title 35 due to another patent on an invention that is not patentably distinct from but was owned by or subject to an obligation of assignment to the same person shall expire on the date of the other patent. A patent whose term has been disclaimed under section 235 independent of another [**14] patent shall be reduced by the length of the originally disclaimed period.

Summary Judgment, at 4-5 (quoting S. Rep. No. 103-412, at 229 (1994)) (emphases added). Applying this explanation of the statutory language, the district court found: "Bayer used language indicating interdependence between several patents." Id. For example, the disclaimer recites "the earlier of the expiration dates of . . ." which modifies the date by its source. Id. The disclaimer also states that Bayer "agrees" that the '444 patent "shall be enforceable only for and during such period that legal title to U.S. Patent No. 4,670,444 shall be the same as legal title to U.S. Patent Nos. 4,544,658 and 4,556,658." Id. at 10. Accordingly, the court concluded that the disclaimed term of the '444 patent was "due to" the Peterson '658 patent, rather than "independent of" that patent. Id. This court discerns no error in the trial court's conclusion.

CTI argues that the trial court should have resolved any ambiguity in the terminal disclaimer in favor of the public. CTI argues that Bayer renounced its rights in the '444 patent after October 1, 2002, and thereby dedicated part of the term of [**15] that patent to the public. According to CTI, the public was entitled to rely on Bayer's disclaimer.

Bayer's original terminal disclaimer recited the October 1, 2002 date as a correct application of the law then in effect. When the URAA altered patent terms, Bayer acted in a timely manner to rectify any ambiguity. Bayer petitioned the PTO to withdraw the disclaimer within one month of the adoption of the URAA amendments. Moreover, the PTO's decision on Bayer's petition became part of the public record on January 31, 1996, more than five years before CTI filed its ANDA in April 2001. Hence, CTI, as well as the public, undisputedly had access to the PTO's interpretation of Bayer's original terminal disclaimer at the time CTI filed its ANDA. Thus, Bayer's prompt action precluded any prejudice to CTI or the public.

Page 5

298 F.3d 1377, *; 2002 U.S. App. LEXIS 16710, **;
64 U.S.P.Q.2D (BNA) 1045

Finally, as Bayer points out, "no patentee could have anticipated the URAA patent extension" at the time Bayer filed its terminal disclaimer in 1992. The "October 01, 2002" date was simply the date of expiration of the Peterson '658 patent as calculated under then-existing law. Furthermore, Bayer disclaimed part of the '444 patent term pursuant to its ANDA related suit against [**16] Barr to defend against Barr's allegation that the '444 patent was invalid for double patenting over the two '658 patents. Thus, in context, Bayer intended to disclaim the term from the "earlier of the expiration dates of U.S. Patents Nos. 4,544,658 (issued October 1, 1985) and 4,556,658 (issued December 3, 1985)." Terminal Disclaimer.

As the district court correctly noted: "Bayer thereby voluntarily abandoned the protected term on the '444 patent to the extent that it exceeded the earlier patent, and agreed to enforce the '444 patent only up to the date

on which the Peterson '658 patent would expire." Summary Judgment, at 2. Because the URAA amendments automatically changed the expiration date of the Peterson '658 patent from October 1, 2002 to December 9, 2003, the [*1383] expiration date of the '444 patent, which is contingent upon the expiration date of the Peterson '658 patent, also changed simultaneously to December 9, 2003.

III.

In sum, the district court properly upheld the PTO's determination that the expiration date of the '444 patent as it relates to ciprofloxacin is December 9, 2003.

COSTS

Each party shall bear its own costs.

AFFIRMED.

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NOV 30 2004

PATENT S/N 09/933,918

REISSUE PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-------------------|---|----------------------|------------------|
| Patent Applicant: | LEE ET AL. | Examiner: | ARTHUR L. CORBIN |
| Serial No.: | 09/933,918 | Group Art Unit: | 1761 |
| Filed | 08/21/2001 | Docket No.: | 8436.18USRE |
| Confirmation No.: | 2055 | Original Patent No.: | 5,637,345 |
| Title: | METHOD OF MANUFACTURING POWDERED DEER BLOOD | | |

**PETITION UNDER 37 C.F.R. § 1.182 TO CORRECT
THE RECORD IN ERROR REGARDING TERM OR
TO AMEND THE TERMINAL DISCLAIMER FILED
IN ERROR TO A JOINT MISTAKE BY APPLICANTS
AND THE PATENT OFFICE EXAMINER**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned on behalf of Applicants for the reissue for METHOD OF MANUFACTURING POWDERED DEER BLOOD, U.S. Patent No. 5,637,345 granted to Applicants on June 10, 1997, respectfully petitions to either:

1. Correct the record regarding term by accepting the attached Certificate of Correction; or
2. Accept an amended terminal disclaimer that corrects a mistake that is apparent on the disclaimer and on the face of the patent made jointly by Applicants and the Patent Office Examiner.

The facts of the case shows that the terminal disclaimer at issue arose from a mistake made initially by the Applicants. The mistake was compounded by the Examiner during proceedings regarding the rejection. The terminal disclaimer filed should have recited that the term was limited to the term of Lee et al., U.S. Patent No. 5,505,980. The patent listed on the face of the patent and in the terminal disclaimer is a patent having nothing to do with the family of patents.

The disclaimer cannot be used as a general disclaimer. The facts of this case are not in dispute. Applicants filed a terminal disclaimer containing a mistake clear on its face. The Patent Office Examiner reviewing the disclaimer did not recognize the error. It cannot be said that the disclaimer was a general disclaimer of the term of the patent since it was made specifically in response to a double patenting rejection and was intended to disclaim any portion of the term of the patent that would extend past the termination of its parent, U.S. Patent No. 5,505,980. Applicants have filed a reissue application to correct this joint error. The reissue application is pending awaiting the decision regarding the terminal disclaimer error. Applicants were advised by the reissue Examiner that Applicants were required to remove the original incorrect terminal disclaimer. In an earlier decision on petition, the Patent Office has refused to withdraw that disclaimer. We believe the Examiner has erred in that position.

In this paper, Applicants are withdrawing the initial petition to withdraw the erroneous terminal disclaimer and now petition the Patent Office to either (1) accept a Certificate of Correction to correct a mistake in the record regarding term¹ or (2) accept an amended terminal disclaimer correcting errors made and compounded by the Applicants and the Patent Office Examiner.

In the attached paper, Applicants distinguish the authority relied on by the Petitions Examiner. The *Bayer* case does not relate to the facts of this case, since in the *Bayer* case, no error was made. The *Bayer* case clearly suggests that in the situation, such as the instant case, where a mistake is made that is plain on the face of the terminal disclaimer and the patent, that the mistakes are correctable by reissue by either correcting the record regarding term, as was done in the *Bayer* case, or by amending the mistake in the terminal disclaimer.

¹ Petitioner believes that the certificate should have been accepted when filed originally.

Requested Relief in View of the Above

Applicants request that the terminal disclaimer filed on 6 September 1996 be corrected or that the patent be corrected by the attached Certificate of Correction.

Respectfully submitted,

29 Nov '04
Date



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NOV 30 2004

ATTACHMENT: AMENDED DISCLAIMER**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Y. S. Lee et al. Examiner: A. Corbin
Serial #: 08/584,748 Group Art Unit: 1302
Filed : January 11, 1996 Docket: 08436.18US11
Title : HEALTH FOOD PRODUCT INCLUDING POWDER MADE FROM DEER
BLOOD AND A METHOD OF MANUFACTURING THEREFOR

TERMINAL DISCLAIMER TO OBLIGATE
A DOUBLE PATENTING REJECTION

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Petitioners' representative, on behalf of Petitioners, Youn S. Lee, residing at 4 March Place, Belfast, Christchurch, New Zealand; and Hyung S. Lee, residing at 125-3 Kalak-Dong, Songpa-Ku, Seoul, Korea, represents that National Deer Horn Limited having a place of business at 4 March Place, Belfast, Christchurch, New Zealand, is the owner of the entire right, title and interest in U.S. Patent Application Serial No. 08/584,748, filed on January 11, 1996 and entitled, HEALTH FOOD PRODUCT INCLUDING POWDER MADE FROM DEER BLOOD AND A METHOD OF MANUFACTURING THEREFOR.

Petitioners' representative hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term of U.S. Patent No. 5,460,677 and hereby agrees that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to U.S. Patent No. 5,460,677, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantee, its successors, or assigns.

In making the above disclaimer, Petitioners' representative does not disclaim the terminal part of any patent granted on the

5,505,980

SN 08/584,748

M-G 08436.18US11

above-identified application that would extend to the full statutory term as presently shortened by any terminal disclaimer of U. S. Patent No. ~~5,460,677~~, in the event that any such issued patent expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321(a), has all claims cancelled by a reexamination certification, or is otherwise terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date

September 6, 1996

Janice Sharp
Attorney for Applicants
Registration No. 34,051

Please charge Deposit Account No. 13-2724 any fees necessary for this Terminal Disclaimer.

THE STATEMENT BELOW IS FOR OFFICE USE ONLY

In accordance with the decision granting the Petition filed on , 19 , this Terminal Disclaimer is accepted. The period of patent lapse specified above has been accepted as equivalent to months.

Date

Petitions Examiner

NOV 30 2004

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.: 5,637,345 Docket: 8436.18USRE
Issue Date: JUNE 10, 1997 Patentee: LEE ET AL.
Title: METHOD OF MANUFACTURING POWDERED DEER BLOOD

REQUEST FOR CERTIFICATE OF CORRECTION

Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

It is requested that a Certificate of Correction be issued correcting printing errors appearing in the above-identified United States patent. One copy of the text of the Certificate in the suggested form is enclosed.

As some of the errors listed are due to Applicant's mistake, our check in the amount of \$100.00 is enclosed to cover the Certificate fee.

Issuance of the Certificate of Correction would neither expand nor contract the scope of the claims, and re-examination is not required.

Respectfully submitted,

28 Nov 04
Date

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PATENT TRADEMARK OFFICE

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,637,345

PAGE 1 of 1

DATED : JUNE 10, 1997

INVENTOR(S) : Youn S. Lee and Hyung S. Lee

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page of the patent, first Column, paragraph [*] Notice:, third line,

delete the patent number "5,460,677" and

insert therefor --5,505,980--.

MAILING ADDRESS OF SENDER:
Merchant & Gould P.C.
Attn: Mark DiPietro
P.O. Box 2903
Minneapolis, MN 55402-0903

PATENT NO. 5,637,345
Docket No. 8438.18USRE
No. of add'l copies 0

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PATENT TRADEMARK OFFICE